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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,133	03/08/2005	Francesco Sias	4462-13	9432
	7590 12/12/200 NDERHYE, PC	EXAMINER		
901 NORTH G	LEBE ROAD, 11TH F	NIA, ALIREZA		
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
			3739	
			MAIL DATE	DELIVERY MODE
			12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Summary	10/527,133	SIAS, FRANCESCO				
Office Action Summary	Examiner	Art Unit				
The MAN INC DATE of the	Alireza Nia	3739				
- The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA:  Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period was reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE.	1.  nety filed  the mailing date of this communication.  D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 04 Oc	1) Responsive to communication(s) filed on <u>04 October 2005</u> .					
2a) This action is <b>FINAL</b> . 2b) ⊠ This	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
·	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) ⊠ Claim(s) <u>25-48</u> is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>25-48</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration.					
Application Papers		•				
9) The specification is objected to by the Examine 10) The drawing(s) filed on <u>08 March 2005</u> is/are: a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	a)  accepted or b)  objected to drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) ⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ⊠ All b) □ Some * c) □ None of:  1. ☑ Certified copies of the priority documents have been received.  2. □ Certified copies of the priority documents have been received in Application No  3. ☑ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 03/08/05.</li> </ol>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate				

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#### DETAILED ACTION

### **Drawings**

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **reference number** 6, page 8, line 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## **Specification**

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. On lines 2, 3, 5, 6, and 7 of the abstract, the term "said" has been repeatedly used.

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### Claim Objections

4. Claim 38 is objected to because of the following informalities: typographical error. On line 2 of the claim, the word "an hand" should be -- a hand --. Appropriate correction is required.

# Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 32, 33, 39-42 and 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 32, the recitation "an edge positioned in such a way that it faces the operator during use" is indefinite since the "the operator" cannot be part of the claim and without the operator as a reference, it is unclear which side the edge is positioned during use.

# Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 25-36 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budding 5,464,412 in view of Kaji 6,142,931.
- 9. With respect to claims 25-28, Budding discloses an anoscope (fig. 1), comprising a first hollow body 4 (col. 2, lines 44-46) open at opposite ends (fig. 1) and a second hollow body 6

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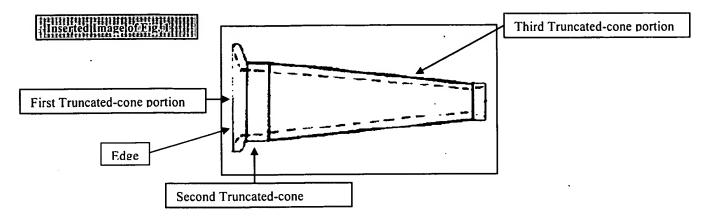
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open at opposite ends (fig. 1) shapingly coupled with said first hollow body 4 and arranged coaxially inside said first hollow body 4.

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- 10. However, Budding does not disclose the second hollow body coaxially rotating inside the first hollow body, the second hollow body being provided with a window arranged to make a portion of rectal mucous membrane accessible, wherein said window has dimensions and a shape such as to enable a surgical device to intervene on said portion. Budding also does not disclose an angular positioning element arranged to adjust the relative angular position of the second hollow body in the first hollow body in preset reciprocal angular positions.
- 11. Kaji teaches a second hollow body coaxially rotatable inside a fist hollow body, the second hollow body being provided with a window 32 arranged to make a portion 34 of rectal mucous membrane accessible, wherein said window 32 has dimensions and a shape such as to enable a surgical device 38 (figs. 4, 5A) to intervene on said portion 34 (col. 9, lines 65-67 and col. 10, lines 5-17). Kaji also teaches an angular positioning element 6 arranged to adjust the relative angular position of the second hollow body in the first hollow body in preset reciprocal angular positions via 25,28,29 (col. 8, lines 58-61 and col. 9, lines 24-35).
- 12. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Budding in view of the limitations taught by Kaji in order to provide an endoscope guide tube unit for allowing an endoscope to be inserted therein and a treatment tool to be inserted therein so that, while observing an affected region under the endoscope, the affected region is treated, as taught by Kaji (col. 3, lines 53-57).
- 13. With respect to claims 29-31, Budding in view of Kaji disclose the invention as discussed above. Budding further teaches the first hollow body comprises a first truncated-cone portion, wherein first truncated-cone portion is solidly connected with a second truncated-cone portion

that has a progressively decreasing cross-section, wherein the second truncated-cone portion is solidly connected with a third truncated-cone portion that has a progressively decreasing cross-section (see inserted image of fig. 1 below).



- 14. With respect to claim 32, Budding in view of Kaji disclose the invention as discussed above. Budding further teaches an edge (see inserted image of fig. 1 above) positioned in such a way that it faces the operator during use. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the first truncated-cone portion as the proximal end closest to the operator in order to load surgical instruments.
- 15. With respect to claims 33-36 and 38-45, Budding in view of Kaji disclose the invention as discussed above. Kaji further teaches the second hollow body comprises a rotation segment 25 and an operating segment 4 that can be associated with one another before use via 6 (col. 8, lines 19-22, 49-50, 58-61). Kaji also teaches the window 32 is arranged on the operating segment 4 (fig. 1A) wherein the window 32 comprises an operating window (fig. 5) An anoscope according to claim 32, wherein said second hollow body comprises a rotation segment and an operating segment, that can be associated with one another before use. Kaji also teaches notche 29.

  Moreover, Kaji teaches the angular positioning element 6 is integral with the rotation segment 25

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(col. 8, lines 58-61), wherein the angular positioning element 6 comprises a plurality of teeth (fig. 1B), wherein the plurality of teeth comprises a locking tooth (fig. 1B).

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- 16. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Budding in view Kaji, further in view of the limitations taught by Kaji in order to provide an endoscope guide tube unit for allowing an endoscope to be inserted therein and a treatment tool to be inserted therein so that, while observing an affected region under the endoscope, the affected region is treated, as taught by Kaji (col. 3, lines 53-57).
- 17. With respect to the recitations in claims 38 and 42, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device such that the desired outcome would have been achieved, since it has been held that, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A).
- 18. With respect to the recitations in claims 39 and 40, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included more than one notch as required to achieve the desired outcome since, duplicating the components of a prior art device is a design consideration within the skill of the art. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).
- 19. With respect to claim 42, it would have been obvious to one of ordinary skill in the art at the time of the invention to have arranged the notches along the edge as necessary to achieve the desired outcome since, it has been held that rearranging parts of an invention involves only routine skill in the art, In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

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20. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Budding 5,464,412 in view of Kaji 6,142,931 further in view of Block 4,834,067.

- 21. Budding in view of Kaji disclose the invention as discussed above. However, Budding in view of Kaji do not disclose the operating window to be defined by a U-shaped cut.
- 22. Block teaches an operating window 18a that is defined by a U-shaped cut (fig. 2).
- 23. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Budding in view of Kaji, further in view of the limitations taught by Block in order to provide a novel speculum to afford an unassisted proctologist with working access to the hemorrhoids for obliterative suture, as taught by Block (col. 2, lines 4-7).
- 24. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budding 5,464,412 in view of Kaji 6,142,931 further in view of Boebel 4,538,594.
- 25. Budding in view of Kaji disclose the invention as discussed above. Kaji further teaches an elastic sealing element 19 (col. 8, lines 43). However, Budding in view of Kaji do not disclose the locking tooth comprises a recess housing a peg.
- 26. Boebel teaches a recess 3a housing a peg 11 (col. 3, lines 15-17).
- 27. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Budding in view of Kaji, further in view of the limitations taught by Boebel in order to provide a resectoscope to secure access to the rectum without surgical intervention, whilst at the same time being able to make use of all auxiliary instruments needed for intestinal surgery, as taught by Boebel (col. 1, lines 16-20).
- 28. With respect to claim 48, it would have been obvious to one of ordinary skill in the art at the time of the invention to have recognized that the locking of the angular positioning element could have been done by an interaction between the peg and the notches, with the peg getting

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caught in the notches to restrict movement, since it has been held that rearranging parts of an invention involves only routine skill in the art, In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alireza Nia whose telephone number is 571-270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alireza Nia

December 7<sup>th</sup>, 2007

LINDA C. M. DVORAK PORY PATENT EXAMINER

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